

REMARKS

In response to the Office Action mailed July 16, 2003, Applicants amended claim 1. Claims 1-14 are pending.

Written Description Rejection

The Examiner rejected claims 1-11 under 35 U.S.C. §112, first paragraph for allegedly failing to satisfy the written description requirement. In making this rejection, the Examiner referred to guidelines published in the Federal Register and stated that:

Although the specification discloses a few possible “compounds” (see Specification, Examples), the specification and claims do not provide any guidance as to what structural features all of these “compounds” share ... The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. (Office Action at page 6, emphasis original).

Thus, the Examiner's basis for the rejection seems to be founded in a belief that the specification does not adequately describe the compounds covered by claims 1-11.

However, upon reviewing the guidelines referred to by the Examiner, Applicants have found not support for a written description rejection based on the above-quoted statement.¹ Rather, according to the guidelines referred to by the Examiner, the written description requirement may be satisfied:

by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled a known or disclosed correlation between function and structure, or some combination of such characteristics. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. (Federal Register, Vol. 66, No. 4, page 1106, Friday, January 5, 2001).

¹ If an appropriate legal basis exists that would support a written description rejection based on the quoted statement, Applicants request that the Examiner provide a specific citation to the legal basis.

This is exactly what the specification provides. The specification provides numerous classes of compounds that can be used, and also provides an example in which 1600 compounds were tested. (*Specification* at page 3, lines 23-27, page 7, line 29-page 8, line 17 and Fig. 2). The specification also refers to Szejtli, J. et al., "Introduction and General Overview of Cyclodextrin Chemistry", **1998**, *Chem. Rev.*, 98, 1743-1753 ("Szejtli"), which discloses a substantial amount of information regarding, for example, the chemical structures and properties of cyclodextrins. Thus, upon reading the specification, one skilled the art would understand that Applicants had possession of the invention covered by claims 1-11 in accordance with the written description requirement of 35 U.S.C. §112, first paragraph. (*See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).

In view of the foregoing, Applicants request reconsideration and withdrawal of this rejection.

Enablement Rejection

The Examiner rejected claims 1-11 under 35 U.S.C. §112, first paragraph for purportedly failing to satisfy the enablement requirement. In *In re Wands* 858 F.3d 731 (Fed. Cir. 1998), the United States Court of Appeals for the Federal Circuit described the factors to be considered and balanced when determining whether a disclosure satisfies the enablement requirement. Each of these factors is discussed below with respect to claims 1-11.

The nature of the invention:

As it relates to claim 1, the invention is directed to compound libraries that include at least 100 compounds, where each compound within the library is stored in the presence of a cyclodextrin and the cyclodextrin concentration is 20-200mM. Claims 2-11 depend from claim 1, and add further features thereto. Claims 2 and 3 require the libraries to include at least 1000 compounds and at least 10000 compounds, respectively. Claims 4 and 5 require the compounds to be organic molecules of molecular weight of less than 2000 Daltons and less than 1000 Daltons, respectively. Claims 6, 7, 8 and 9 require the cyclodextrin concentration to be 30-

150mM, 40-80mM, 45-60mM and 50mM, respectively. Claim 10 requires the cyclodextrin to be 2-hydroxypropyl- β -cyclodextrin. Claim 11 requires the libraries to be in wet form.

The level of one of ordinary skill in the art:

The level of skill of one of ordinary skill in the art is relatively high. In general, one of ordinary skill in the art would likely have a Ph.D. in chemistry and would be familiar with compound libraries.

The state of the prior art:

No one has previously disclosed or suggested compound libraries that include at least 100 compounds, where each compound within the library is stored in the presence of a cyclodextrin and the cyclodextrin concentration is 20-200mM (claim 1), and certainly has not disclosed or suggested the particular compound libraries covered by claims 2-11.

The breadth of the claims:

The limitations of claims 1-11 are noted above.

The level of predictability in the art:

The relevant art is generally unpredictable. However, as discussed below, the present application discloses sufficient information to allow one of ordinary skill in the art to successfully implement the compound libraries covered by claims 1-11.

The existence of working examples:

Applicants submitted appropriate experimental data for preparing a compound library with 80 compounds and a library with 1600 compounds.

The amount of direction provided by the inventor:

The present application provides sufficient direction to one of ordinary skill in the art to successfully implement the compound libraries covered by claims 1-11. Applicants provided guidance with respect to examples of chemical classes that can be included in the libraries and the number of chemical classes that can be included in the compound libraries. (*See, e.g., Specification* at page 3, lines 20-27). Applicants also provided guidance with respect to various other features of the technology, such as the number of compounds in the libraries (*see, e.g., id.* lines 8-14), the molecular weight of the compounds in the libraries (*see, e.g., id.* lines 17-19), the

concentration of cyclodextrin in the libraries (*see, e.g., id.* lines 28-31), a particular type of cyclodextrin that can be used (*see, e.g., id.* at page 7, line 30-page 8, line 17), and the form of the compound libraries (*see, e.g., id.*). Applicants provided further guidance regarding the general structural and chemical properties of cyclodextrins. (*see, e.g., id.* at page 5, lines 23-24).

The quantity of experimentation needed to make or
use the invention based on the content of the disclosure:

The specification discloses ample information regarding various aspects of the relevant technology. Provided with this information, undue experimentation would not be necessary for one skilled in the art could to successfully practice the subject matter covered by claims 1-11. Rather, the experimentation would be considered as rather routine to one of ordinary skill in the art.

In view of the foregoing, Applicants request reconsideration and withdrawal of this rejection.

§102 Rejections

The Examiner rejected claims 1-11 under 35 U.S.C. §102(a) as being anticipated by EP 0 947 820 A2 ("Henco"). However, Henco is not prior art to the present application under 35 U.S.C. §102(a) because, while the present application has a priority date of August 24, 1999, Henco was not published until October 6, 1999.² Applicants therefore request reconsideration and withdrawal of this rejection.

The Examiner rejected claims 1 and 4-11 under 35 U.S.C. §102(b) as being anticipated by WO 98/06831 (Castillo), EP 0 609 766 A2 (Nishiki), and/or Tabushi, I. et al., "Specific

² The Examiner rejected Applicants' claim to priority because, according to the Examiner, Applicants failed to submit a certified copy of the Swedish priority patent application in accordance with P.C.T. Rule 17. In fact, Applicants submitted a certified copy of the Swedish priority patent application to the International Bureau ("the IB") as required by P.C.T. Rule 17. The IB has orally confirmed to Applicants that the IB received the certified copy of the Swedish priority patent application. Applicants therefore believe that they are in compliance with P.C.T. Rules 17.1(a) and 17.1(b). Thus, Applicants believe that, under P.C.T. Rule 17.2, Applicants are not responsible for forwarding a copy of the priority document to the U.S.P.T.O., but, rather, that the U.S.P.T.O. is responsible for requesting a copy of the priority document from the IB. Notwithstanding this, Applicants have now asked the IB to send a copy of the priority document to the U.S.P.T.O. But, because it appears that the U.S.P.T.O. is responsible for obtaining a copy of the priority document, Applicants ask the U.S.P.T.O. to investigate this situation and take the requisite action to be certain that the U.S.P.T.O. obtains a copy of priority document from the IB.

Inclusion Catalysis by β -Cyclodextrin in the One-Step Preparation of Vitamin K1 or K2 Analogues," *J. Am. Chem. Soc.*, **1979**, 101 (4), 1019-1026 ("Tabushi"). As amended, claims 1 and 4-11 cover compound libraries that include at least 100 compounds, where each compound within the library is stored in the presence of a cyclodextrin. Neither Castillo, Nishiki nor Tabushi disclose such compound libraries. Applicants therefore request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) based on Castillo, Nishiki and Tabushi.

§103 Rejections

The Examiner rejected claims 1-9 and 11 under 35 U.S.C. §103(a) as being unpatentable over Tabushi. As noted above, Tabushi does not disclose the compound libraries covered by claims 1-9 and 11. Nor is there any suggestion to modify Tabushi to provide such compound libraries. Tabushi is concerned with cyclodextrins as a reaction catalyst for particular compounds relating to vitamin K. The mere fact that compound libraries were known is not in and of itself sufficient motivation to somehow use the compounds disclosed in Tabushi to provide the compound libraries covered by claims 1-9 and 11. Further, Tabushi appears to disclose only five compounds in cyclodextrin. (*See Tabushi* at page 1020, column 2). Thus, even if one skilled in the art were somehow motivated to modify Tabushi to use his compounds to provide a compound library, the resulting library would not include at least 100 compounds, where each compound within the library is stored in the presence of a cyclodextrin, as required by claims 1-9 and 11. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 1-9 and 11 under 35 U.S.C. §103(a) based on Tabushi.

The Examiner rejected claims 1 and 4-11 under 35 U.S.C. §103(a) as being unpatentable over Tabushi and Castillo. However, as noted explained, Tabushi does not disclose or suggest the subject matter covered by claims 1 and 4-11.

Castillo does not cure Tabushi's infirmities. First, whereas Tabushi is directed to compounds relating to vitamin K, Castillo is interested in finding a preservative that works in the presence of cyclodextrin. As a result, one skilled in the art would not have even been motivated to combine the teachings of Tabushi and Castillo in the first place. Moreover, Castillo discloses

individual compounds in the presence of cyclodextrin and a preservative. Nowhere does Castillo disclose a library include at least 100 compounds where each compound within the library is stored in the presence of a cyclodextrin, as required by claims and 4-11.

Neither Tabushi nor Castillo, alone or in combination, disclose or suggest the compound libraries covered by claims 1 and 4-11. There is no suggestion to combine these references to provide such libraries. Further, even if Tabushi and Castillo were combined, the result would not be a compound library including at least 100 compounds, where each compound within the library is stored in the presence of a cyclodextrin, as required by claims 1 and 4-11. Applicants therefore request reconsideration and withdrawal of the rejection of claims 1 and 4-11 under 35 U.S.C. §103(a) based on Tabushi and Castillo.

Information Disclosure Statement

Applicants appreciate the Examiner's suggestion to properly submit references cited in the specification of the present application. The subject references are Henco (referred to above) and Szejtli. However, Henco is already of record (cited and applied by the Examiner), and Applicants have already submitted Szejtli in an Information Disclosure Statement. The Information Disclosure Statement including Szejtli was submitted subsequent to the mailing of the present Office Action, and should be considered by the Examiner in conjunction with the present Reply.

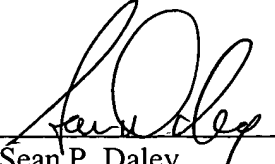
Applicants believe the application is in condition for allowance, which action is requested. Enclosed is a to cover fees associated with a two month extension of time in connection with responding to the Office Action mailed July 16, 2003. Please apply any other charges or credits to deposit account 06-1050.

Applicant : Per-Ola Arvidsson et al.
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Respectfully submitted,

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Sean P. Daley
Reg. No. 40,978

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906